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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,999	12/29/2003	Rozalina Dimitrova	17638 (BOT)	8259

7590 03/07/2006

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EXAMINER	
HUH, BENJAMIN	
ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,999	DIMITROVA ET AL.	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/4/05 & 12/29/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to injection guide, classified in class 604, subclass 116.

II. Claims 11-12, drawn to method for assisting botulinum toxin therapy, classified in class 604, subclass 500.

III. Claims 13-14, drawn to method for determining an area of pain and/or allodynia, classified in class 128, subclass 898.

Inventions I and II and III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the injection guide can be used as a guide for allergy shots or injecting a different material than botulinum toxin.

During a telephone conversation with Stephen Donovan on 2/22/2006 at 6:11 pm a provisional election was made with traverse to prosecute the invention of Group I, claims 1-10. Affirmation of this election must be made by applicant in replying to this

Office action. Claims 11-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

Claim 3 is objected to because of the following informalities: on line 2 of claim 3 it states "when the material is pressed again the dermal area ...", the spelling is assumed to be "...against ..." instead of again. Appropriate correction is required.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 11 & 12 of the second group should be renumbered as 13 & 14. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardiner (US Patent No. 4228796). The Gardiner reference discloses in figures 1-5 an injection guide comprising a material having an upper face and a lower face, wherein the material has an exterior border which circumscribes the material and wherein the exterior border is not perforated and wherein the material is flexible so that when the material is pressed against the dermal area, substantially all of the exterior border is in contact with the dermal area, the lower face of the material being suitable for placement in contact with an area of the dermis of a patient to or through which dermal area a botulinum toxin can be administered, the material having a plurality of staggered perforations 32 which extend completely through the material from the upper face to the lower face, and wherein at least some of the perforations are spaced apart by a uniform distance and wherein the injection guide of Gardiner would be inherently capable of assisting a botulinum toxin therapy due to it's size, shape, and ability to work in the environment.

With regards to claims 7-10, the material comprises a plurality of contiguous circles wherein the perforations 32 are located in the center of the circles as seen in figures 1-5.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Katz (US Patent No. 4642096). The Katz reference discloses in figures 1& 2 an injection guide comprising a material having an upper face and a lower face, wherein the material has an exterior border which circumscribes the material and wherein the

exterior border is not perforated and wherein the material is flexible so that when the material is pressed against the dermal area, substantially all of the exterior border is in contact with the dermal area, the lower face of the material being suitable for placement in contact with an area of the dermis of a patient to or through which dermal area a botulinum toxin can be administered, the material having a plurality of staggered perforations seen as multiple openings labeled in col. 5 lines 30-60 which extend completely through the material from the upper face to the lower face, and wherein at least some of the perforations are spaced apart by a uniform distance and wherein the injection guide of Gardiner would be inherently capable of assisting a botulinum toxin therapy due to it's size, shape, and ability to work in the environment.

With regards to claims 7-10, the material comprises a plurality of contiguous circles wherein the perforations are located in the center of the circles as seen in figures 1 & 2.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Kaauwen (WIPO Pub. WO02/068028A1). The Van Kaauwen reference discloses in figures 1& 2 an injection guide comprising a material having an upper face and a lower face, wherein the material has an exterior border which circumscribes the material and wherein the exterior border is not perforated and wherein the material is flexible so that when the material is pressed against the dermal area, substantially all of the exterior border is in contact with the dermal area, the lower face of the material being suitable for placement in contact with an area of the dermis of a patient to or through which

dermal area a botulinum toxin can be administered, the material having a plurality of staggered perforations seen as holes 10 which extend completely through the material from the upper face to the lower face, and wherein at least some of the perforations are spaced apart by a uniform distance and wherein the injection guide of Gardiner would be inherently capable of assisting a botulinum toxin therapy due to it's size, shape, and ability to work in the environment.

With regards to claims 7-10, the material comprises a plurality of contiguous circles wherein the perforations are located in the center of the circles as seen in figures 1 & 2.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Huitema et al (US Pub No. 2002/0177807), Mick et al (US Patent no. 6579262B1), Whitmore, III et al (US Patent No. 6036632), and Arana (US Patent No. 4798212) all disclose injection guides with circular perforations placed in a uniform distance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BHH

BHH

MJ Hayes

MICHAEL J. HAYES
PRIMARY EXAMINER